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10/081,347

02/21/2002

Theresa A. Deisher

96-20C5

2963

7590

11/22/2006

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,347

Applicant(s)

DEISHER ET AL.

Examiner

Christine J. Saoud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/17/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claims 1, 4, 7, 10, 13, and 16 have been amended in the amendment filed 07 April 2006. Claims 1-18 are under examination in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 07 April 2006 have been fully considered., but are not persuasive for the reasons provided below.

Claim Rejections - 35 USC § 112

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding the polypeptide of SEQ ID NO:2 and for polynucleotides encoding a polypeptide that is 95% identical to SEQ ID NO:2, wherein the encoded polypeptide stimulates proliferation of cells derived from mesenchymal stem cells or their precursors, does not reasonably provide enablement for polynucleotides encoding polypeptides that have 80-95% identity with a portion of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims for the reasons of record in the previous Office action.

Applicant argues that a functional limitation has been added to the claimed molecules and that the specification teaches assays for determining function. Applicant

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also asserts that the specification teaches two conserved regions of zFGF5 (a heparin binding domain and an FGF conserved region). Applicant's arguments have been fully considered but are not persuasive.

The instant specification discloses a protein which is a member of the FGF family of proteins (and polynucleotides encoding this protein). Proteins of the FGF family share significant structural similarity (as evidenced by Figure 1 of the instant specification), however, these proteins do not share a common function or a function that can be predicted by amino acid sequence similarity (see pages 1-4 of the specification). The instant specification has not identified that portion of the disclosed protein that is critical for the biological activity zFGF5. The instant specification has not identified those amino acids which are critical for biological activity. The instant specification has not made any modifications to the natural amino acid sequence of the disclosed protein. However, the claims are directed to molecules which differ from the disclosed protein by as much as 50%. This number comes from the fact that claim 1 only requires 80% amino acid sequence identity, but this % identity is only over a fraction of the protein (60%). The specification may disclose that the region from amino acid 55 to 175 of SEQ ID NO:2 is the most highly conserved portion of the protein, but this does not mean that this is the critical portion of the molecule which is responsible for biological activity. For example, the N-terminal portion of KGF (also called FGF-7) is critical to the protein's specificity for keratinocytes. This fact could not be determined from amino acid sequence similarity to other members of the FGF family. The instant claims encompass a multitude of molecules with no recitation of function and the

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specification provides no guidance on how to use molecules which do not have the function attributed to the protein of SEQ ID NO:2. Additionally, the specification provides no examples, guidance, expectation of success of making molecules which differ from the amino acid sequence of SEQ ID NO:2 by as much as 50% (80% in the region from amino acid 55 to 175 of SEQ ID NO:2) which function in a manner such that one of ordinary skill in the art could use these molecules. The skill in the area of the biotech arts is considerable, however, in the absence of examples, guidance, and predictability in conjunction with the breadth of the claims and experimentation required to practice the invention, the claims are merely a "wish to know" and are not enabled, absent evidence to the contrary.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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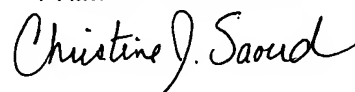
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Christine J. Saoud". The signature is written in a cursive, flowing style.